REMARKS

With this Amendment, Claims 8, 9, 18, 19, 29, 30 and 33-72 have been canceled without prejudice as being drawn to a non-elected invention or species, Claims 1-7, 10, 11 and 20 have been canceled without prejudice, Claims 12, 13 and 22 have been amended and Claims 73-81 have been added. Thus, after entry of this Amendment, Claims 12-17, 21-28, 31, 32 and 73-81 are pending in the instant Application. Applicants expressly reserve the right to prosecute claims drawn to canceled subject matter in one or more continuation, divisional or continuation-in-part applications.

AMENDMENT OF CLAIMS AND NEW CLAIMS

Claim 12 has been amended to clarify that the recited invention is a method of providing neuroprotection. Support for the amendment may be found in the Specification at page 20, line 25 to page 21, line 9 and page 53, line 35 to page 54, line 22. Claim 13 has been amended to recite that the subject has a neurological disorder, neurodegenerative disease or CNS injury. Support for this amendment is found in originally filed Claim 12 and the Specification at page 54, lines 4-5. Claim 22 has been amended to recite that the neurological disorder is caused by brain or spinal cord trauma. Support for this amendment may be found in originally filed Claim 13..

Support for Claim 73 may be found in originally filed Claim 22. Claims 74 and 78, Claims 75 and 79, Claims 76 and 80 and Claims 77 and 81 encompass various embodiments of the invention and are supported by the Specification at page 34, lines 5-8, page 34, lines 10-19, page 34, lines 25-30 and page 35 lines 4-7, respectively.

No new matter is added by the amendment of Claims 12, 13 and 22 and the addition of Claims 73-81. Accordingly, entry into the instant Application is proper and respectfully requested.

REJECTION UNDER 35 U.S.C. § 112, first paragraph

Claims 11-17, 20-28 and 31-32 stand rejected under 35 U.S.C. § 112, first paragraph for lacking an enabling disclosure. The rejection is moot with respect to Claim 11 and traversed with respect to Claims 12-17, 21-28 and 31-32.

In order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph a patent application, supplemented with information known in the art, need only teach one of ordinary skill in the art how to make and use the invention, without conducting undue experimentation. The patent disclosure is not required to teach, and preferably omits that which is well known in the art. *In re Buchner*, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 USPQ 481, 489 (Fed. Cir. 1984). Experimentation typically engaged in by those of skill in the art is permitted, as long as the experimentation is not undue. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976).

A disclosure, as filed, is presumed to be enabled, unless there is reason to objectively doubt the truth of the statements relied on for enabling support. *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971). Thus, the Patent Office bears the initial burden of presenting a reasonable explanation of why the scope of protection sought in the claims is not enabled by the specification. *In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

As an initial matter, Applicants note that the rejection provides no explanation for why Claims 23-28 and 31-32, which are drawn to a method for enhancing cognitive function, are not allegedly enabled by the Specification. Since the Examiner has failed to present a reasonable explanation for rejecting Claims 23-28 and 31-32, the initial presumption of an enabled disclosure has not been rebutted. *In re Marzocchi*, 169 USPQ at 370. Accordingly, there is "no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *Id.*

Nevertheless, in the interests of expediting prosecution, Applicants submit that Claims 23-28 and 31-32 are fully enabled by the Specification. Applicants teach general methods for synthesizing compounds with cognition enhancement activity (Specification, page 45, line 20 to page 47, line 20) and provide examples that describe the preparation of specific compounds with cognition enhancement activity (Specification, page 63, line 1 to page 67, line 15). Applicants also teach methods for testing compounds of the invention for cognition enhancing activity (Specification, page 53, line 35 to page 54, line 20) and provide examples in art-recognized animal models that demonstrate the cognition enhancing properties of the compounds of the invention (Specification, page 86, line 34 to page 87, line

19, page 88, line 34 to page 91, line 2). Therefore, the Specification teaches how to make and use the invention recited in Claims 23-28 and 31-32, without undue experimentation. Nothing more is required under 35 U.S.C. § 112, first paragraph.

Applicants do not agree with the rejection as applied to originally filed Claim 12-17 and 20-22 and further note that the rejection is also incorrect with respect to amended Claims 12-17, 21 and 22, which now recite a method of providing neuroprotection. Applicants now address several issues raised in the Examiner's rejection of originally filed claims 12-17 and 20-22, which remain relevant to amended Claim 12-17, 21 and 22.

An inventor is not required to describe or even know how or why his invention works to obtain a patent. *Newman v. Quigg*, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989). Thus, an inventor does not need to understand or describe the scientific basis for the practical utility of his invention. *Fromson v. Advanced Offset Plate, Inc.*, 219 USPQ 1137, 1140 (Fed. Cir. 1983). Further, an observation of a physiological phenomenon is "not inherently suspect simply because the underlying basis for the observation cannot be predicted or explained." *In re Cortright*, 49 USPQ2d 1464, 1469 (Fed. Cir. 1999).

With regard to the Examiner's conclusion on page 3 of the current Office Action, that the prior art has "recognized the ineffectiveness of therapeutics on the regeneration of motor neurons after a CNS injury," Applicants note that the Examiner has failed to supply any evidence to support this assertion. Further, the conclusions and opinions of the prior art are irrelevant, since Examples 8 and 9 of the instant Application demonstrate efficacy of the compounds of the invention in providing neuroprotection in art-accepted animal models. Nothing more is required under 35 U.S.C. § 112, first paragraph. Applicants simply are not charged by the statute with describing or understanding how or why the compounds of the invention work in order to obtain a patent on their use for providing neuroprotection.

With regard to the Examiner's statement on page 4 of the Office Action that the "specification has not provided any guidance on the effectiveness of the compounds on motor neurons that do not have the ability to recover which is a characteristic of neurological disorders such as ALS and spinal cord injuries," Applicants are entitled to a generic claim without exemplifying every possible embodiment of that generic claim. Applicants are not required by 35 U.S.C. § 112, first paragraph to provide guidance or working examples of every possible embodiment of the invention.

Further, Applicants' demonstration that the compounds of the invention provide neuroprotection in art-accepted tests is not negated because no guidance or working examples proving regeneration of motor neurons has been provided by the Specification. Applicants have shown that the compounds of the invention provide neuroprotection in art-recognized animal models, which is all that is required under 35 U.S.C. § 112, first paragraph.

The rejection, as presently formulated, does not provide a reasonable explanation for why claims that recite a method of providing neuroprotection are not enabled by the Specification. Thus, for the reasons advanced above in discussing the rejection of Claims 23-28 and 31-32, Applicants are not required to support their presumptively accurate disclosure.

However, in order to facilitate prosecution, Applicants direct the Examiner to portions of the Specification that teach how to make and use the invention recited in amended Claims 12-17 and 21-22, without undue experimentation. Applicants teach general methods for synthesizing compounds that exhibit neuroprotective activity (Specification, page 45, line 20 to page 47, line 20) and provides examples that describe preparation of specific compounds with neuroprotective activity (Specification, page 63, line 1 to page 67, line 15). Applicants also teach methods for testing the compounds of the invention for neuroprotective activity (Specification, page 53, line 35 to page 54 line 20) with examples that demonstrate neuroprotection by the compounds of the invention in art-accepted animal models (Specification, page 86, line 2 -33, page 87, line 30 to page 88, line 30 and page 91, line 24 to page 97, line 3).

Evidence, which is well known to those of ordinary skill in the art, may be provided to supplement a specification in overcoming an enablement rejection. *In re Howarth* 210 USPQ 689 (CCPA 1981). Such evidence should provide facts rather than conclusory statements. *In re Bradstadter* 179 USPQ 286, 293 (CCPA 1981).

Thus, as additional evidence of the efficacy of the compounds of the invention in providing neuroprotection in a variety of art-accepted *in vitro* tests, Applicants refer the Examiner to Exhibit B, a Declaration under 37 C.F.R § 1.132 made by co-inventor Alan I. Faden on November 2, 1999, in parent U.S. Application Serial No. 09/022,184, now abandoned. In particular, pages 5-9 of the Declaration describe the *in vitro* tests, while Exhibits 2-8 of the Declaration illustrate the results that demonstrate neuroprotection by the compounds of the invention in these *in vitro* tests.

For the reasons advanced above, Applicants submit that the Specification teaches how to make and use the invention recited in Claims 12-17 and 21-22, without undue experimentation, which is the legal standard for enablement under 35 U.S.C. § 112, first paragraph. In view of the foregoing, Applicants respectfully request that the rejection of Claims 12-17, 21-28 and 31-32 under 35 U.S.C. § 112, first paragraph be withdrawn.

REJECTION UNDER 35 U.S.C. § 102

Claims 1-7 and 10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Stadler *et al.*, FR 1583797. Claims 1-7 and 10 have been canceled, which renders these rejections moot.

CONCLUSION

Applicants respectfully submit that all pending Claims of the captioned Application satisfy all requirements for patentability and are in condition for allowance. Therefore, Applicants respectfully request a Notice of Allowance for this Application.

If the Examiner determines that prosecution of the instant application would benefit from a telephone interview, the Examiner is invited to call the undersigned attorney at (212) 790-6578.

Respectfully submitted,

Date 10/23/03

45,298

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